

**REMARKS**

It is acknowledged that the foregoing amendments are submitted after final rejection. However, because the amendments do not introduce new matter or raise new issues, and because the amendments either place the application in condition for allowance or at least in better condition for appeal, entry thereof by the Examiner is respectfully requested.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

**I. Status of Claims**

With this submission no claims are canceled. Claim 39 is currently amended. Claim 40 is newly added. Hence, upon entry of this paper, claims 1-5, 10, 16-22, 24, 29-31, 34-36, and 38-40 will remain pending and under active consideration.

Support for claim 40 can be found throughout the specification. In particular, support can be found in the specification, page 3, lines 7-17.

From the Advisory Action dated October 26, 2010, the Office states that the amended claims would be rejected under 35 U.S.C. §102/103. Applicants respectfully traverse the rejection.

**II. Claim Rejection- 35 U.S.C. §102- WO 99/36099**

Claims 1-5, 10, 16-22, 24, 28-36 and 38-39 are rejected under 35 U.S.C. § 102, as allegedly anticipated over WO 99/36099 ("the WO '099 reference"). Specifically, the Office states that "Applicant's earlier work in WO '099 teach a method of making sustained release composition (title) [with] the same compound formula species." (Advisory Action, continuation sheet) Applicants disagree.

As an initial matter, Applicants note that the Office has already considered this reference. In particular, the WO99/36099 corresponds to US Patent No. 6,740,634, which was submitted and considered by the Examiner on September 29, 2009 in an IDS (line A17).

A claim in a patent application is anticipated (*i.e.*, lacks novelty) if all of its elements are present in a **single** reference in the prior art. Thus, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The WO '099 reference cannot anticipate the claimed invention, because the WO '099 reference does not teach each and every element of the claims. In particular, the WO '099 reference does not disclose the use of "acetic acid in a molar amount of about 1.5 to about 5 times that of the compound with a solution of lactic acid-glycolic acid polymer in a low water-soluble organic solvent" as required by the claims. In fact, nowhere in the WO '099 reference is there any mention of the use of acetic acid, much less the use of acetic acid in a specific molar concentration.

### **III. Claim Rejection- 35 U.S.C. §103- WO 99/36099 in view JP applications**

Claims 1-5, 10, 16-22, 24, 28-36 and 38-39 are rejected under 35 U.S.C. § 103, as allegedly anticipated or obvious over WO 99/36099 ("WO '099 reference"). The Office recognizes that the molar amounts of the polymer are not disclosed in the WO '099 reference. Nevertheless, the Office argues that it would have been obvious to one of ordinary skill in the art to "optimize any of the formulation elements." (Advisory Action, continuation sheet) However, the Office notes that "absent evidence of the contrary that the same is not present in WO '099 and that any difference provide some unexpected result." (Advisory Action, continuation sheet) Applicants respectfully traverse the rejection.

Again, as an initial matter, these references have already been considered by the Office. In particular, JP 1216918 corresponds to US Patent No. 5,100,669 which was cited in the Office action of October 8, 2009 and not cited in the Final Office action of July 6, 2010. The other applications, JP 2124814 (corresponding to US Patent No. 5,271,945) and JP 4208217 do not specifically describe the compound in the claims, therefore these JP applications do not supplement the WO 99/36099 or JP 1216918 references.

#### A. Unexpected Results

When one considers the obviousness of a combination of known elements, the operative question is “whether the improvement [in combining elements found in the prior art] is more than the predictable use of [the] elements according to their established functions.” MPEP § 2141(I), citing *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396 (2007). “While obviousness does not require absolute predictability, *at least some degree of predictability is required.*” MPEP § 2143.02(II) (emphasis added).

The use of acetic acid produces unexpected results. In particular, “Experimental Example 1” shows that the viscosity only slightly increases when using the formulation described by the claims. In contrast, “Comparative Example 1” shows that viscosity greatly increases when acetic acid was not added, which causes a problem in production. Thus, inventors were the first to find that a W/O type emulsion can be stabilized by using an aqueous solution containing acetic acid in an amount greater than the physiologically active substance.

#### B. JP 1216918 Teaches Away from the Claimed Invention

Further, applicants note that JP 1216918 (corresponding to US Patent No. 5,100,669, “Hyon”) has already been considered and overcome in the Amendment dated April 5, 2010. Applicants have already shown that Hyon actually teaches away from the claimed invention. In particular, Table 2 of Hyon shows that **the method cannot provide the desired effects**. Applicants believed that the Office acknowledged that these arguments overcame the rejection, as the obviousness rejection was not cited in the Office action dated July 6, 2010.

#### C. None of the Cited References Teach the Claimed Invention

When determining whether a claim is obvious, an examiner must make “a searching comparison of the claimed invention – *including all its limitations* – with the teaching of the prior art.” *In re Ochiai*, 71 F.3d 1565, 1572 (Fed. Cir. 1995) (emphasis added). Thus, “obviousness requires a suggestion of all limitations in a claim.” *CFMT, Inc. v. Yieldup Intern. Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) (*citing In re Royka*, 490 F.2d 981, 985 (CCPA 1974)). Moreover, as the Supreme Court recently stated, “*there must be some*

*articulated reasoning* with some rational underpinning to support the legal conclusion of obviousness.” *KSR Int’l v. Teleflex Inc.*, 127 S. Ct. 1727, 1741 (2007) (quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added)). The failure of an asserted combination to teach or suggest each and every feature of a claim remains fatal to an obviousness rejection under 35 U.S.C. § 103 and MPEP 2143.03.

As noted above in Section II, the WO ‘099 reference does not teach every element in the claims. Additionally, none of the cited JP references cure this deficiency. In particular, none of the JP references teach the use of acetic acid to decrease the viscosity of the W/O type emulsion. Furthermore, as noted above, the Hyon reference actually teaches away from the claimed invention.

**CONCLUSION**

Applicants believe that the present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing or a credit card payment form being unsigned, providing incorrect information resulting in a rejected credit card transaction, or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicants hereby petition for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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By



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